

Serial No. 10/618,977

PATENT

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1 1-9. (Cancelled).
- 1 10. (Currently amended). A coated medical device comprising:
2 an inflatable balloon having a base material, a hydrophilic material
3 posited on the base material and a balloon bioactive material posited on ~~said base~~
4 ~~material~~ the hydrophilic material.
- 1 11. (Currently amended). The coated medical device according to claim 10,
2 further comprising an implantable stent including a stent base material layer and a
3 stent bioactive material posited on the stent base material layer, wherein said stent
4 is disposed around said balloon.
- 1 12. (Previously presented). The coated medical device according to claim 10,
2 wherein the balloon bioactive material posited on the balloon base material is
3 lipophilic.
- 1 13. (Previously presented). The coated medical device according to claim 11,
2 wherein the balloon bioactive material is lipophilic and extends beyond the ends of
3 the stent disposed around said balloon.

Serial No. 10/618,977

PATENT

1 14. (Currently amended). The medical device according to claim 11, wherein the
2 stent base material layer comprises at least one of: a biocompatible metal, a non-
3 biocompatible polymer and a biodegradable polymerstainless steel, tantalum,
4 titanium, nitinol, gold, platinum, inconel, iridium, silver, tungsten, or another
5 biocompatible metal, or alloys of any of these, carbon or carbon fiber, cellulose
6 acetate, cellulose nitrate, silicone, polyethylene terephthalate, polyurethane,
7 polyamide, polyester, polyorthoester, polyanhydride, polyether sulfone,
8 polycarbonate, polypropylene, high molecular weight polyethylene,
9 polytetrafluoroethylene, or another biocompatible polymeric material, or mixtures
10 or copolymers of these; polylactic acid, polyglycolic acid or copolymers thereof, a
11 polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or another
12 biodegradable polymer, or mixtures or copolymers of these; a protein, an
13 extracellular matrix component, collagen, fibrin or another biologic agent; or a
14 suitable mixture of any of these.

1 15. (Cancelled).

1 16. (Currently amended). The medical device according to claim 10, wherein
2 the base material layer comprises at least one of: irradiated polyethylene,
3 polyethylene terephthalate, polyurethane, polyamide, polyester, polyorthoester,
4 polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular
5 weight polyethylene, polytetrafluoroethylene, or another a biocompatible
6 polymeric material, or mixtures or copolymers of these; polylactic acid,
7 polyglycolic acid, or copolymers of polylactic acid and polyglycolic acidthereof, a
8 polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or another a
9 biodegradable polymer, PEBAX, and nylon, or mixtures or copolymers of these
10 materials.

- 3 -

Serial No. 10/618,977

PATENT

1 17. (Cancelled).

1 18. (Cancelled).

1 19. (Currently amended). The coated medical device according to claim 10,
2 wherein the balloon_bioactive material ~~layer~~ comprises at least one of: paclitaxel,
3 a taxane or other paclitaxel analogue; estrogen or estrogen derivatives; heparin or
4 another thrombin inhibitor, hirudin, hirulog, argatroban, D-phenylalanyl-L-poly-L-
5 arginyl chloromethyl ketone, or another antithrombogenic agent, or mixtures
6 thereof; urokinase, streptokinase, a tissue plasminogen activator, or another
7 thrombolytic agent, or mixtures thereof; a fibrinolytic agent; a vasospasm inhibitor;
8 a calcium channel blocker, a nitrate, nitric oxide, a nitric oxide promoter or another
9 vasodilator; an antimicrobial agent or antibiotic; aspirin, ticlopidine or another
10 antiplatelet agent; vascular endothelial growth factor (VEGF) or analogues thereof;
11 colchicine or another antimittotic, or another microtubule inhibitor; cytochalasin or
12 another actin inhibitor; a remodeling inhibitor; deoxyribonucleic acid, an antisense
13 nucleotide or another agent for molecular genetic intervention; a cell cycle inhibitor
14 (such as the protein product of the retinoblastoma tumor suppressor gene, or
15 analogues thereof); GP IIb/IIIa, GP Ib-IX or another inhibitor or surface glycoprotein
16 receptor; methotrexate or another antimetabolite or antiproliferative agent; an anti-
17 cancer chemotherapeutic agent; dexamethasone, dexamethasone sodium
18 phosphate, dexamethasone acetate or another dexamethasone derivative, or
19 another anti-inflammatory steroid; prostaglandin, prostacyclin or analogues thereof;
20 an immunosuppressive agent (such as cyclosporine or rapamycin); an antibiotic
21 (such as streptomycin), erythromycin or vancomycin; dopamine, bromocriptine
22 mesylate, pergolide mesylate or another dopamine agonist; ⁶⁰Co, ¹⁹²Ir, ³²P, ¹¹¹In,
23 ⁹⁰Y, ^{99m}Tc or another radiotherapeutic agent; iodine-containing compounds, barium-

Serial No. 10/618,977

PATENT

24 containing compounds, gold, tantalum, platinum, tungsten or another heavy metal
 25 functioning as a radiopaque agent; a peptide, a protein, an enzyme, an extracellular
 26 matrix component, a cellular component or another biologic agent; captopril,
 27 enalapril or another angiotensin converting enzyme (ACE) inhibitor; ascorbic acid,
 28 alphotocopherol, superoxide dismutase, deferoxamine, a 21-aminosteroid (lasaroid)
 29 or another free radical scavenger, iron chelator or antioxidant; angiopeptin; a ¹⁴C-,
 30 ³H-, ¹³¹I-, ³²P- or ³⁶S-radiolabelled form or other radiolabeled form of any of the
 31 foregoing; or a mixture of any of these.

1 20. (Cancelled).

1 21. (Cancel)

1 22. (Currently amended) The coated medical device of claim ~~21~~10, where the
 2 ~~layer~~ comprising the hydrophilic material is a slip coating ~~layer~~.

1 23. (Currently amended) The coated medical device of claim 10, where the
 2 balloon bioactive material is lipophilic and comprises paclitaxel, a taxane or other
 3 paclitaxel analogue, ~~and where the coated medical device further comprises a~~
 4 ~~hydrophilic material posited between the base material and the balloon bioactive~~
 5 ~~material.~~

1 24. (Previously presented). A coated medical device comprising:
 2 an inflatable balloon having an expandable outer surface,
 3 a hydrophilic material posited on the expandable outer surface; and
 4 a lipophilic balloon bioactive material posited on the expandable outer
 5 surface.

Serial No. 10/618,977

PATENT

1 25. (Previously presented). The coated medical device of claim 24, where the
2 lipophilic balloon bioactive material comprises a bioactive selected from the group
3 consisting of: an immunosuppressive agent and a compound that inhibits arterial
4 smooth muscle cell proliferation.

1 26. (Previously presented). The coated medical device of claim 24, where the
2 balloon bioactive material comprises paclitaxel.

1 27. (Withdrawn). A method of manufacturing a coated medical device comprising:
2 providing an inflatable balloon having inflated and deflated
3 configurations;
4 inflating the inflatable balloon, the inflatable balloon comprising a
5 balloon base material;
6 depositing a hydrophilic layer on the balloon base material; and
7 depositing a bioactive material on the hydrophilic layer.

1 28. (Withdrawn). The method of claim 27, where the bioactive material is
2 lipophilic.

1 29. (Withdrawn). The method of claim 27, where the hydrophilic layer is
2 deposited on the balloon base material while the inflatable balloon is in the inflated
3 configuration.

1 30. (Withdrawn). The method of claim 27, where the bioactive material is
2 deposited while the inflatable balloon is in the inflated configuration.

Serial No. 10/618.977

PATENT

1 31. (Withdrawn). The method of claim 27, where the balloon base material
2 comprises at least one of irradiated polyethylene, polyethylene terephthalate,
3 polyurethane, polyamide, polyester, polyorthoester, polyanhydride, polyether
4 sulfone, polycarbonate, polypropylene, high molecular weight polyethylene,
5 polytetrafluoroethylene, or another biocompatible polymeric material, or mixtures
6 or copolymers of these; polylactic acid, polyglycolic acid or copolymers thereof, a
7 polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or another
8 biodegradable polymer, PEBAX, nylon or mixtures or copolymers of these.

Please enter the following new claims:

1 32. (New) A coated medical device comprising:
2 an inflatable balloon having an expandable outer surface,
3 a hydrophilic material posited on the expandable outer surface; and
4 a lipophilic balloon bioactive material posited on the expandable outer
5 surface; and
6 an implantable stent including a stent base material disposed around the
7 balloon.

1 33. (New). The coated medical device according to claim 32, wherein the
2 stent further comprises a stent bioactive material posited on the stent base
3 material.

1 34. (New) The coated medical device according to claim 33, wherein the
2 stent bioactive material is selected from the group consisting of: an
3 immunosuppressive agent and a compound that inhibits arterial smooth muscle cell
4 proliferation.